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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,870	08/10/2006	Michal Svoboda	J507-006 US	4078

21706 7590 04/08/2008

NOTARO AND MICHALOS
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SUITE 110
ORANGEBURG, NY 10962-2100

EXAMINER	
EBRAHIM, NABILA G	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,870	SVOBODA ET AL.	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motola et al. US 5024997 (Motola) in view of EP 0 490 193 (EP), machine translation and further in view of Small et al. Pharmacokinetic and Taste Evaluation of Ibuprofen (Motrin®) 800mg Tablets in Extemporaneous Solution, *Journal of Reumatology* 1988 Feb; 15(2):345-7 (Small).

Motola teaches palatable ibuprofen aqueous base solutions which contain dissolved therein ibuprofen, hydroxypropyl beta cyclodextrin and a sweetening agent; the sweetening agent may include sorbitol and glycerin (see examples). Such solutions have utility in pharmaceutical preparations for oral administration (see abstract and examples). The amount of ibuprofen is 2% w/v (see examples 1-5). The ratio between ibuprofen and cyclodextrin compound is about 1:12 (see examples 1-4). Sorbitol is used in the solution (examples 1-4). Further, Motola teaches that the hydroxypropyl beta cyclodextrin was added and dissolved therein. The solution was heated to 50ºC. while mixing and the ibuprofen was added. Mixing was continued until the solution was clear while maintaining 50º C.

Motola discloses ibuprofen; however, the disclosure is deficient in disclosing the specified enantiomer of ibuprofen.

EP teaches complexes of S(+)-ibuprofen and hydroxypropyl beta-cyclodextrin in a weight ratio of 0,01 - 2,0. Said complexes can be used in syrups (see example 10). The reference teaches the use of lemon flavor in the composition.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ibuprofen enantiomer because EP teaches that under

physiological conditions it was found that the water solubility of S (+), Ibuprofen beta - Cyclodextrin complex has a better solubility than ibuprofen itself and that the unwanted smell, taste and the disturbing effect on the mucous membrane diaphragm of the Ibuprofens are decreased (see page 5 of the machine translation).

EP does not disclose the reason of using the lemon flavor.

Small teaches a study to determine the pharmacokinetic and palatability characteristics of ibuprofen. Changes in T_{max}, peak concentration achieved and area under curve were noted with kinds of flavors such as coca-cola solution. A conclusion was made that cherry syrup solution and orange juice are preferred for palatability and bioavailability of ibuprofen.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a citrus flavor to induce palatability and ensure bioavailability of the drug in the form of syrup. Thus the skilled artisan would have excellent expectation of a preparing a palatable syrup containing S(+)-ibuprofen, hydroxypropyl beta-cyclodextrin which is palatable and have good bioavailability. The expected result would be a palatable syrup containing S(+)-ibuprofen, hydroxypropyl beta-cyclodextrin, water and a sweetener.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618